December 15, 2014

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: **"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" Proposed rule; supplemental notice of proposed rulemaking (Docket No. FDA-2011-N-0921 / RIN 0910–AG35)**

To Whom It May Concern:

On behalf of our members, the Produce Marketing Association (PMA) respectfully submits the following comments to the proposed rule entitled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" supplemental notice of proposed rulemaking (Docket No. FDA-2011-N-0921 / RIN 0910–AG35). In addition to this executive summary, PMA submits the attached document that provides specific comments on the proposal. To assist both FDA and our PMA membership in reviewing the comments, we have organized them into specific categories and have also provided the titles and relevant passages (blue print) from the proposed rules to provide context to our comments. The general categories we have organized our comments around are as follows:

I. Overarching Issues
   a. Background
   b. Enforceable Standards Versus Flexibility
   b. Efficacy of Produce Regulation Provisions
   c. Produce and Preventive Controls Rule Coverage

II. Comments on Specific Provisions Set Forth in the Supplemental Produce Rule Proposal
   a. The Definitions of "Farm," "Harvesting," "Holding," and "Packing"
   b. Produce Rule Exclusion of Farms having <$25,000/year in Produce Sales
   c. Agricultural Water Preventive Controls
   d. Biological Soil Amendments of Animal Origin Preventive Controls
   e. Highlighted Protections of Endangered Species
   f. Withdrawal and Reinstatement of a "Qualified Exemption"

PMA is the largest trade association representing companies in the fresh fruits and vegetables industry. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate at every level in the supply chain; from growing to shipping, processing/manufacturing, distribution, wholesaling, retail

and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

PMA's vision is to strengthen and lead the global produce community to increase produce consumption. Fruits and vegetables are an integral part of a nutritious and healthful diet, offering great public health benefits. PMA believes that produce safety, taste, convenience, and nutrition are the cornerstones of increasing fruit and vegetable consumption and fighting obesity.

PMA has long been a champion of produce safety and has relied upon the expertise of produce safety professionals who serve as volunteer leaders on the PMA Science & Technology Committee and PMA members at large to develop the comments that follow. In preparing our comments, PMA engaged in numerous and frequent in-depth discussions with PMA member companies that grow, pack and ship fresh produce both domestically and internationally and companies that represent the diversity of produce commodities American consumers expect to be available to them year around. Throughout the discussion, PMA members carefully discussed and deliberated the ability of each proposed produce safety rule provision to enhance public health, while searching for practicable and easily implementable solutions to enhance the safety of fresh produce. As a result, our comments provide perspectives from the collective experiences of those who work diligently in the produce global supply chain to provide safe and nutritious produce to consumers daily.

PMA is also a strong supporter of the development of scientific and technical information, as indicated by the association's founding support of the Center for Produce Safety (CPS). CPS is a unique research foundation focused exclusively on produce-related food safety research in collaboration with industry, government and academia. CPS provides open access to scientific research results that are actionable and necessary to continually enhance the safety of produce. Companies of all sizes and locations benefit from CPS research. The research results generated by CPS have added significantly to the body of knowledge associated with produce safety. Scientific research regarding produce safety plays an important and integral role in informing produce company food safety practices, best practices guidance developed by industry and government, and rule-making policy decisions. However, there are significant data and research gaps regarding on-farm produce safety preventive controls, which make finalization of FDA produce safety standards in some areas difficult, if not impossible, and significant investment in on-farm food safety research will be required. While there is currently ongoing industry sponsored research at institutions like the CPS regarding means to ensure the safe use of biological soil amendments of animal origin and agricultural water, more research is needed before mandated numerical preventive controls should be imposed.

**Executive Summary**

Food safety is a top priority for the global produce industry. Implications of these proposals are critically important to PMA members' businesses and to the industry's overall objective of increasing produce consumption. PMA strongly supports advancing produce safety in ways that are meaningful for industry members and that also protect public health, including through the implementation of the Food Safety Modernization Act. PMA supports the implementation of science- and risk-based regulations throughout the supply chain that require the use of preventive controls that correspond with risks associated with the commodity, practices and procedures employed during the production, handling and holding of fresh produce.

Key issues from the perspective of PMA members regarding FDA's produce safety rule supplemental proposal are as follows:

- Produce Rule Scope and Coverage (Exemptions and Exclusions)
- Produce and Preventive Controls Rule Coverage
- Premature Use of Mandated Numerical Preventive Control Standards
- Produce Rule Implementation

<u>Produce Rule Scope and Coverage (Exemptions and Exclusions)</u>
All produce growers need to minimize the potential for microorganisms of public health significance on produce regardless of the product, where and how it's grown and handled, particular business size and market channel or geographic radius. PMA strongly supports that all farms should perform an assessment of risk for their operations and develop and implement a food safety plan with specific preventive controls to address likely microbial hazards and routes of contamination. FDA has a statutory obligation to promote and protect the public health of all consumers who receive food products from all market channels, not just for certain market channels. Therefore, PMA has taken the following policy positions in our comments regarding the produce rule supplemental proposal.

*Exclusion of farms with less than $25,000 in annual food sales:* PMA opposes this exclusion based solely on revenue (<$25,000 annual food sales) and recommends that this exclusion be eliminated. Exclusion of farms with less than $25,000 in annual food sales is not science- or risk-based. Produce contamination can occur in any operation that uses unsafe processes and practices. There is no scientific basis to support the exclusion.

*Qualified Exemption (Tester/Hagen Amendment):* PMA opposes the "qualified exemption" and recommends that this exemption be eliminated. PMA understands that FDA is statutorily obliged to provide this "qualified exemption," however, it should be noted that the "qualified exemption" is not science- or risk-based, as food safety risks are not limited to any particular business size, market channel or geographic radius. Produce contamination can occur in any operation that uses unsafe processes and practices. There is no scientific basis to support the qualified exemption. PMA supports the administrative

procedures that FDA has proposed regarding withdrawal of a qualified exemption; reinstatement of a "qualified exemption" when FDA determines, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the farm that had its qualified exemption withdrawn. PMA does not support inclusion of administrative procedures for the reinstatement of withdrawn qualified exemption in the case where the farm has been linked to a foodborne illness outbreak. The FSMA statute does not provide for reinstatement of the qualified exemption, and FDA should not provide for requalification and reinstatement of a withdrawn qualified exemption. Once a qualified exemption has been withdrawn due to a foodborne illness being associated with produce from a specific farm, a permanent withdrawal of the qualified exemption should occur, with no possibility for reinstatement.

Produce and Preventive Controls Rule Coverage

PMA recommends that FDA align the requirements of the produce and preventive controls rules for the produce industry. There is very serious produce industry concern that the regulatory lines of coverage between the produce safety rule and preventive controls for human foods rule are not workable for agriculture and do not reflect the realities of produce production and handling. For example, as proposed, an on-farm produce packing house would be regulated under the produce rule, an off-farm packing house with less than $1 million dollars in total food sales would be subject to the Current Good Manufacturing Practices (CGMP) provisions of the preventive controls rule for human food and an off-farm packing house with more that $1 million dollars in total food sales would be subject to both the GMP and Hazard Analysis and Risk-Based Preventive Controls (HARPC) provisions of the preventive controls rule for human foods.

There is no science-based reason for treating a packing house differently based on where raw agricultural commodities (RACs) are packed or an enterprise's size. Produce packing houses are not materially or compositionally changed or altered and do not undergo any manufacturing or processing activities and thus should be regulated under the produce rule.

Redefining "farm" to include establishments that are solely engaged in "packing" and "holding" activities performed on RACs would allow packinghouse operations to be considered "farm" establishments and be covered by the produce safety rule. This provides uniform and effective regulation of all packing activities, irrespective of physical location or enterprise size, to be solely covered by the produce safety regulation. The definition of "farm" need not be predicated on the fact that growing must occur to consider an establishment a "farm."

Premature Use of Mandated Numerical Preventive Control Standards

PMA opposes FDA-mandated quantitative preventive control standards in the final regulation to ensure the safe use of agricultural water and raw manure as a soil amendment, as more research is needed before situation-specific quantitative preventive controls can be defined.

*Quantitative Agricultural Water Microbial Standards:* PMA does not support the use of quantitative generic *E. coli* levels as the criteria in the regulation to determine when agricultural water is not of safe and adequate sanitary quality for the following reasons:

- **Currently Proposed Agricultural Water Provisions Are Overly Complex and Overly Prescriptive**. Setting a single quantitative preventive control standard for agricultural water is a "one size fits all" approach because a single quantitative standard would not adequately take into consideration numerous contributing factors that affect the risk of contamination and the probability of subsequent illness.
- **Use of Generic *E. coli* as Agricultural Water Microbial Quality Indicator is Not Appropriate**. The body of scientific knowledge clearly demonstrates that there is currently inadequate scientific evidence to establish quantitative metrics based solely on the use of generic *E. coli* as an indicator organism.
- **Use the U.S. EPA RWQC as an Indicator of Agricultural Water Microbial Quality Criteria is Not Appropriate.** Use of the U.S. Environmental Protection Agency (EPA) Recreational Water Quality Criteria (RWQC) as the basis for an agricultural water standard is an extrapolation of the U.S. EPA data set. Specifically, the U.S. EPA RWQC assumes direct personal ingestion of the recreational water and correlates that event to the prevalence of subsequent illnesses. Direct consumer consumption of agricultural water simply does not occur, which makes extrapolation and quantification of the recreational water risk assessment to agricultural water highly questionable and imprecise at best.
- **Use of a Geometric Mean and Statistical Threshold Value for Evaluating Agricultural Water Microbial Quality Are Not Universally Appropriate.** Currently proposed provisions that require farmers to calculate a "geometric mean" and "statistic threshold value" to characterize the microbial quality of their agricultural water are overly complex to be accomplished on a regular basis by individual farmers. Additionally, the total number of samples required for the agricultural water characterization is excessive in number, economically burdensome and will be problematic from a laboratory capacity perspective.
- **Agricultural Water Application-to-Harvest Time Intervals Need Refinement.** FDA's proposed constant linear microbial die-off rate unbounded by any time constraints is problematic in that it is likely to lead growers to erroneous conclusions regarding the long-term die-off of microbes on produce.

*Quantitative Application to Harvest Intervals for Untreated Soil Amendments of Animal Origins:* PMA supports the concept of an application-to-harvest interval for untreated biological soil amendments of animal origin based on an individual entity's operational

assessment of risk. The application-to-harvest interval for untreated biological soil amendments of animal origin should not be tied to a specific quantitative preventive control standard in the regulation. PMA supports that growers should consider the application-to-harvest interval for untreated soil amendments of animal origin but the interval should correspond with risk of soil amendment-to-crop contamination based on the grower's operational assessment of risk. The use of a "one size fits all" quantitative preventive control, is unsupported by science in all cases and hence, it is arbitrary and capricious. Establishment of quantitatively risk-based application-to-harvest intervals for untreated soil amendments is needed but it will require further research that can customize the application-to-harvest interval based on the commodity, agro-ecological growing conditions and practices. Additionally, as new scientific knowledge becomes available, growers must be able to utilize updated and improved knowledge regarding safe application-to-harvest intervals for untreated biological soil amendments of animal origin. PMA is concerned that as more information about application-to-harvest intervals for the use of untreated biological soil amendment of animal origin becomes available the one quantitative criteria set forth in the regulation will be obsolete and not protective of public health, or overly restrictive with little public health benefit and overly burdensome to produce growers.

PMA supports FDA's deferred decision on an appropriate time interval for the use of raw manure as a biological soil amendment of animal origin until research, risk assessment and other efforts are undertaken to support compost infrastructure development.

PMA recommends that FDA take a similar approach regarding setting quantitative preventive control standards for agricultural water until research and risk assessments can be completed so as to be able to enable farmers to make informed decisions regarding the safe use of this important agricultural input.

Produce Rule Implementation

PMA supports the finalization and implementation of FSMA regulations; however, PMA members have very serious concerns regarding many of the proposed provisions set forth in the supplemental proposed produce safety rule and preventive controls rule for human food. Many of the proposed provisions will adversely affect how produce businesses operate, and the proposed provisions simply do not reflect the realities of produce production, handling and storage. It is critically important that FDA get the final produce safety and preventive controls rules right to truly enhance the safety of produce available to the consumer while not adversely affecting how produce businesses operate.

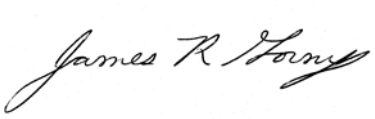
However, the detailed prescriptiveness of the currently proposed produce regulation provisions are particularly disconcerting to numerous produce industry sectors because any deviation from FDA prescribed preventive controls would be considered a prohibited act. Additionally, PMA has concerns that FDA has interpreted the FSMA statute term "enforceable standards" as meaning wherever possible the use of "quantitative standards" in the produce safety rule implementing regulation. It is desirable to have objective

quantitative standards set forth in regulations because they are readily measurable, unambiguous and not easily misinterpreted by either regulators or the regulated community. However, in some cases it is not currently possible to set risk-based and science-based quantitative preventive control standards for some on-farm microbial hazards due to lack of technical information about the risks posed by some on-farm microbial hazards and the efficacy of various preventive controls.

PMA proposes that FDA consider use of qualitative regulatory provisions in the codified preventive control provisions of the produce safety regulation. Qualitative preventive control standards in the codified produce safety implementing regulation in concert with situational specific compliance guidance articulated in FDA Level I guidance to the industry would be highly desirable. This approach prevents creating static quantitative regulatory requirements for all situations that are locked in current 2014 science by allowing for continuous improvement via incorporation of new scientific findings.

PMA has participated in the congressional debate about FSMA and has provided comment to FDA at every opportunity in the development of the proposed rules. We greatly appreciate those earlier opportunities and the opportunity here to provide detailed comments on the rules. Attached are those comments. Thank you for the opportunity.

Respectfully,



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**Produce Marketing Association**

"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"

(Docket No. FDA-2011-N-092 / RIN 0910–AG35)

The Produce Marketing Association (PMA) on behalf of its members respectively submits the following comments in response to the U.S. Food and Drug Administration's (FDA) Federal Register Notice entitled, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" supplemental notice of proposed rulemaking (Docket No. FDA-2011-N-0921 / RIN 0910–AG35) issued on September 29, 2014. PMA is the largest trade association representing companies that market fresh fruits and vegetables. We represent 2,700 companies in 45 countries including members that handle more than 90 percent of fresh produce sold to consumers in the United States. Member companies are representative of the U.S. produce industry supply chain. They vary in size from small to large and their operations range from supermarket retailing, wholesaling, distribution, to shipping and growing. PMA's members of every size and at every level in the supply chain are committed to food safety and share the FDA's focus on food safety. PMA is also a strong supporter of the development of science-based produce safety knowledge to assist industry and government in making informed produce safety decisions, as indicated by the association's support of the Center for Produce Safety (CPS). CPS is a unique research entity focused exclusively on produce-related food safety research in collaboration with industry, government and academia. CPS provides open access to scientific research results that are actionable and necessary to continually enhance the safety of produce. Companies of all sizes and locations throughout the produce value chain benefit from CPS research.

PMA applauds the FDA for the tremendous effort made in developing supplemental proposed produce standards. PMA supports the use of science-based standards in the produce industry. Recognizing the profound impact the final produce rule and other rules currently under development will have on the produce industry, PMA offers its support to the FDA, our membership, related trade associations, USDA and state and local agencies on implementing the final rule and all of its provisions. PMA understands the importance of these rules in preventing produce associated foodborne illnesses and is committed to improving the safety of fresh produce.

PMA's comments are provided below on select topic areas set forth in the FDA's supplemental proposed rule and notice.

## I. Overarching Issues

### a. Background

FSMA is a monumental food safety regulatory change and it is specifically groundbreaking in how FDA will interact with farmers to assure the safe growing, harvesting, packing, and holding of produce for human consumption. Significantly FSMA alters FDA's mode of operations in that FDA will be more proactive in preventing food adulteration and involved in determining on-farm produce safety procedures policies and practices by standard setting and guidance.

### b. Enforceable Standards Versus Flexibility

The detailed prescriptiveness of the currently proposed produce regulation provisions are particularly disconcerting to numerous produce industry sectors because any deviation from FDA prescribed preventive controls would be considered a prohibited act. Additionally, PMA has concern that FDA has interpreted the FSMA statute term "enforceable standards" as meaning wherever possible the use of "quantitative standards" in the produce safety rule implementing regulation. While it is desirable to have objective quantitative standards set forth in regulations because they are readily measurable, unambiguous and not easily misinterpreted by either regulators or the regulated community. However, in some cases it is not currently possible to set risk-based and science-based quantitative preventive control standards for some on-farm microbial hazards due to lack of technical information about the risks posed by some on-farm microbial hazards and the efficacy of various known preventive controls.

Two produce rule provision areas where we believe there is insufficient technical information for FDA to set quantitative preventive control standards are: 1) the microbial quality of agricultural water for growing produce and 2) application-to-harvest intervals for the use of raw manure as a soil amendment to grow produce. Setting a single quantitative preventive control standard for either of these potential two possible routes of microbial contamination, would in essence be taking a "one size fits all" approach because a single quantitative standard would not adequately take into consideration numerous contributing factors that affect the risk of contamination and the probability of subsequent illness. However, we do believe that situational specific quantitative preventive control standards are possible to set but only if there is sufficient technical information and the standards are situation-specific to the procedures and practices employed by the farmer for a specific commodity or group of commodities.

PMA would like to propose that FDA consider use of more flexible regulatory provisions in the codified preventive control provisions of the produce safety regulation, such as for example, those found in sections 21 CFR 110.80 Processes and Controls: *"Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food."*

Specifically it is suggested that FDA consider the following for “agricultural water” in the produce safety regulation: “All agricultural water used for the growing, harvesting and packing of produce must be safe and of adequate sanitary quality for its intended use. Agricultural water may be reused for the growing, harvesting and packing of produce if it does not contaminate the food.”

This level of specificity is what is needed in the codified produce safety implementing regulation and compliance for situational specific procedures and practices should be clearly articulated in FDA Level I guidance to the industry. If FDA does not take this hybrid approach of broad requirements in the implementing regulation, followed by situational specific guidance, it risks creating a static regulatory requirement for all situations locked in current 2014 science that does not allow for continuous improvement, incorporation of new scientific findings or process innovations.

In summary, PMA respectfully requests that at this time FDA not set quantitative microbial agricultural water quality standards or quantitative standards for use of raw manure. While quantitative preventive control standards for these important agricultural inputs is appropriate. A “one size fits all” quantitative requirement put forward at this time would not be appropriate for all commodities. However, if FDA chooses to promulgate quantitative microbial agricultural water quality standards or quantitative standards for use of raw manure agricultural water quality standards in the final produce rule, it should be done only on an “interim” basis until more science-based and risk-based, commodity-specific and situation-specific standards can developed to account for the diversity of procedures, practices and inherent differences among produce commodities. Additionally and importantly, any “interim” standard should have a “sunset provision” associated with it so as to incentivize industry, government and academia to work to together to investigate and develop science-based and risk-based quantitative standards for these two important agricultural inputs.

**c. Efficacy of Produce Regulation Provisions**

As the FSMA produce rule is implemented it will be important for FDA and industry to work collaboratively to quantify how effective or ineffective particular preventive controls provisions made requisite by the produce safety regulation, perform at meeting the FSMA stated public health goal of reducing produce adulteration and subsequent illnesses. It will not be sufficient for FDA to rely solely on the measurement of improved public health outcomes resulting from FSMA produce rule implementation. It will be critical to determine the effect of specific preventive controls mandated by the produce rule provision areas in reducing produce adulteration and foodborne illnesses. This approach will help determine if the regulatory standard for particular provision areas has been set “too high” or “too low.” If FDA does not take this hybrid approach of broad requirements in the implementing regulation coupled with situation-specific guidance, FDA risks imposing standards on the produce industry that do not enhance produce safety in specific provision areas or

saddling the industry with burdensome provisions that may only marginally enhance produce safety. FDA, in the agency's implementation framework, has stated that the agency will in the future act both as a public health agency and a regulatory agency. To act as public health agency, FDA must measure the efficacy of each provision area and have the ability to adjust produce provision areas so that improved public health outcomes can be achieved cost effectively. Without sufficient measurement of provision area efficacy to improve public health and the flexibility to adjust regulatory provisions on a regular basis, FSMA will likely not attain its goal of enhancing public health.

**d. Produce and Preventive Controls Rule Coverage**

It is recommended that FDA align the requirements of the produce and preventive controls rules for the produce industry. A more seamless integration of the two rules would strengthen enforcement and reduce confusion. Growers, handlers and others in the marketing chain will be able to better understand the requirements and direct their attention to those activities that can make products safer. There is very serious produce industry concern that the regulatory lines of coverage between the produce safety rule and preventive controls for human foods rule are not workable for agriculture and do not reflect the realities of produce production and handling. For example, as proposed, an on-farm produce packing house would be regulated under the produce rule, an off-farm packing house with less the $1 million dollars in total food sales would be subject to the Current Good Manufacturing Practices (GMP) provisions of the preventive controls rule for human food and an off-farm packing house with more that $1 million dollars in total food sales would be subject to both the CGMP and Hazard Analysis and Risk-Based Preventive Controls (HARPC) provisions of the preventive controls rule for human foods.

There is no science-based reason for treating a packing house differently based on where raw agricultural commodities (RACs) are packed or quantity packed. Produce is not materially or compositionally changed or altered and does not undergo any manufacturing or processing activities and thus should be regulated under the produce rule.

PMA acknowledges that as per the Food Safety Modernization Act, food facilities that must register with FDA per the requirements of the Bioterrorism Act of 2002 are to be regulated by the preventive controls for human foods regulation. However, this regulatory scenario fails to recognize the basic business structure in the produce industry and the many operational configurations that ensure highly perishable raw agricultural commodities are harvested, sorted, packed and shipped to consumers to meet their demands for healthy, nutritious products.

Redefining "farm" to include establishments that are solely engaged in "packing" and "holding" activities performed on RACs would allow packinghouse operations to be considered "farm" establishments and be covered by the produce safety rule. This provides uniform and effective regulation of all packing activities, irrespective of physical location, to be solely covered by the produce safety regulation. The definition of farm need

not be predicated on the fact that growing must occur to consider an establishment a "farm."

Additionally, PMA has also provided alternative draft definitions for: "Farm," "Harvesting," and "Holding," which if adopted by FDA would provide the opportunity to make the produce rule workable for agriculture and reflect the realities of food production. The proposed framework provided by PMA would mean that all produce packing houses irrespective of their physical location would be considered "farm" establishments for the purposes of coverage under one produce safety regulation.

## II. Comments on Specific Provisions Set Forth in the Supplemental Produce Rule Proposal

### a. Subpart A - Definition of "Farm," "Harvesting," "Holding," and "Packing"

**Subpart A**

**§ 112.3 What definitions apply to this part?**

***Farm*** *means an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes establishments that, in addition to these activities:*

*(i) Pack or hold raw agricultural commodities;*

*(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and*

*(iii) Manufacture/process food, provided that:*

*(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or*

*(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:*

*(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and*

*(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.*

**PMA Comment:** PMA recommends that the definition of "farm" be amended as follows:

***Farm means*** *an establishment where raw agricultural commodities are grown, harvested, packed and/or held, animals are raised (including seafood), or both and have a common, owner, operator(s) or agent in charge and are operated under a common food safety management scheme. The term "farm" includes establishments that, in addition to these activities:*

*(i) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and*
*(ii) Manufacture/process food, provided that:*
*(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or*
*(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:*
*(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and*
*(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.*

- The term "farm" should be redefined to include packing and holding activities performed on RACs, as this allows for packing house operations to be considered "farm" establishments and be covered by the produce safety rule. This provides uniform and effective regulation of all packing activities irrespective of their physical location to be solely covered by the produce safety regulation. The definition of "farm" need not be predicated on the fact that growing must occur to consider an establishment a "farm."
- "One general physical location" is an irrelevant descriptor that cannot be clearly defined without being arbitrary or capricious. Hence, it should be removed from the definition of farm.
- PMA recommends the use of the descriptor "owner, operator, or agent in charge" in the "farm" definition so that the definition is consistent with preventive controls for human foods rule. The proposed descriptor is inclusive of the various individuals that might be responsible for the operation of a "farm." The use of pronouns to refer to the "owner, operator or agent in charge" is appropriate.

**Harvesting** applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use

as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm are examples of harvesting.

**PMA Comment:** PMA recommends that the definition of "harvesting" be amended as follows:

**Harvesting** applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities on a farm. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, ripening (artificial or natural), field coring and cooling raw agricultural commodities grown on a farm are examples of harvesting.

- PMA supports the inclusion of activities traditionally done in the field, such as field coring in the "harvesting" definition.
- Ripening, whether by natural means over time or stimulated by introduction of ethylene for climacteric fruits, is done for the purpose of preparing a raw agricultural commodity for use as a food and hence should be defined as "harvesting" for the purposes of this regulation.
- Ripening is not a manufacturing or processing step as the RAC does not undergo any substantial transformation and is exactly the same food product being introduced into commerce both before and after ripening.

**Holding** means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

**PMA Comment:** PMA recommends the definition of "holding" be amended as follows:

**Holding** means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Fumigation of raw agricultural commodities is an example of a holding activity. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

- Fumigation of raw agricultural commodities is done for the safe effective storage of many fruits and vegetables and should be defined as "holding" for the purposes of this regulation.
- Fumigation is not a manufacturing or processing step as the RAC does not undergo any substantial transformation and is exactly the same food product being introduced into commerce both before and after ripening.

**Packing** means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

**PMA Comment:** PMA agrees with the proposed definition of "Packing."

## b. Subpart A - Produce Rule Exclusion of Farms Having <$25,000/year in Produce Sales

**§ 112.4 Who is subject to the requirements of this part?**

(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of more than $25,000 (on a rolling basis), you are a "covered farm" subject to this part.

**PMA Comment:** PMA opposes produce rule exclusion based solely on revenue (<$25,000 annual food sales) and recommends that this exclusion be eliminated.

- **Food safety is not limited by business size:** Food safety risks are not limited to a particular business size based on revenue and for this reason PMA cannot support exemptions based solely on business revenue. High-risk processes and practices can exist in any operation. Human pathogens know no boundaries based on the economic size of a farm.
- **Revenues are not a science-based measure:** Consumer safety regulations predicated on business size based on revenue is not science based. As per FDA statistics (Regulatory Impact Analysis), farm entities that market less than $25,000 worth of food per year provide a small percent of the overall fresh produce supply available to consumers. However, FDA has a statutory obligation to promote and protect the public health of all consumers whom receive food products from all market channels, not just for certain market channels. This exemption goes beyond what has been mandated in the Food Safety Modernization Act. Minimum food safety requirements implemented across all market channels and sizes of farms would ensure consistency as opposed to two-tiered food safety requirements depending on farm business size based on revenue.
- **Produce related outbreaks impact everyone:** Foodborne illness outbreaks associated with produce adversely impact public health and diminish consumer confidence for a specific produce commodity. These adverse effects are not proportional to business size, as all produce farms large and small in size are adversely economically affected. These widespread adverse effects of a foodborne illness outbreak associated with a particular produce item on the growers whom are not the responsible party are particularly devastating as losses are not covered by insurance and may result in a grower losing their business. These adverse economic consequences to growers whom are not the responsible party to a foodborne illness outbreak are likely greater than the costs of implementing food safety programs irrespective of business size.
- **Unfunded mandate for states:** This exemption places undue economic burden on state, local and tribal governments, as they will now be the agency's which by default will be tasked with on-farm food safety regulatory enforcement on this economic class of entities.
- **Un-equivalent risk associated with $25,000 worth of produce:** The $25,000 total food sales exemption is arbitrary and not science based as a means of measuring exposure to risk. For example, the total volume or product (or number of exposure dosages) that represents $25,000 worth of exempted produce in the U.S. is very different from the volume of product off the same exempted produce when it is grown in an emerging economy. Since the volume of product represented by $25,000 is different, the number of exposures represented is different and hence so is the risk.

- **<$25,000 total food sales companies:** The $25,000 total food sales exemption may permit companies to create new or separate business entities with total food sales of less than $25,000 in order to qualify for an exemption. This creates an uneven business environment for companies that do not engage in such practices and potentially increases public health risk for the whole produce commodity category, thus endangering the livelihood and business viability of companies that are conforming to the FDA produce safety standard.
- **Market access:** Exempting farms with less than $25,000 in total food sales potentially reduces the economic viability of these entities as they will likely no longer be able to sell into desirable retail and foodservice markets due to the perception that the products they produce are less safe because they are not regulated by the FDA produce safety standard. Counterintuitive, this $25,000 total food sales exemption, while intending to relieve these entities of the economic burden associated with the produce safety standard, may in fact unintentionally harm this class of farms in the marketplace by undermining the perceived safety of products from these farms.

## c. Subpart E - Agricultural Water Preventive Controls

**Subpart E**

**§ 112.44 What testing is required for agricultural water, and what must I do based on the test results?**

* * * * *

(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N to develop and verify the water quality profile of the water source as described in § 112.45(b)(1). Using your water quality profile as described in § 112.45(b)(1), if you find that (when applicable) the estimate of the statistical threshold value (STV) of samples exceeds 410 colony forming units (CFU) of generic *E. coli* per 100 mL of water, or if you find that the geometric mean (GM) of samples exceeds 126 CFU of generic *E. coli* per 100 mL of water (or an alternative microbial standard consistent with paragraph (d)(1) of this section), you must either:

(1) Apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (or an alternative microbial die-off rate consistent with paragraph (d)(2) of this section) to achieve a (calculated) log reduction of your geometric mean of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL, or an alternative microbial standard consistent with paragraph (d)(1) of this section;

(2) Apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your geometric mean of generic E. coli level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL (or an alternative microbial standard consistent with paragraph (d)(1) of this section), provided you have adequate supporting scientific data and information. You may apply this time interval in addition to the time interval in accordance with paragraph (c)(1) of this section; or

(3) If options (c)(1) or (c)(2) are not selected, immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either re-inspect the entire agricultural water system under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

(d) You may establish and use alternatives to the following requirements provided you satisfy the requirements of § 112.12:

(1) Microbial quality standard established in paragraph (c) of this section; and

(2) Microbial die-off rate established in paragraph (c)(1) of this section that is used to determine the time interval between last irrigation and harvest.

**§ 112.45 How often must I test agricultural water that is subject to the requirements of § 112.44?**

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

(1) You receive water from a public water system, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(c), you must take the following steps for each source of the untreated surface water:

(1) Conduct a baseline survey to develop a water quality profile of the agricultural water source.

(i) You must conduct a baseline survey in order to initially develop the water quality profile of your water source. You must determine the appropriate way(s) in which the water may be used based on your water quality profile in accordance with § 112.44(c)(1) through (3).

(ii) The baseline survey must be conducted over a minimum period of 2 years by calculating the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli (E. coli)* (colony forming units (CFU) per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. The water quality profile initially consists of the GM and STV of generic *E. coli* calculated using this data set.

(iii) You must develop a new water quality profile:

(A) At least once every 10 years by recalculating the GM and STV values using a minimum total of 20 samples collected during your most recent annual surveys (which are required under paragraph (b)(2) of this section); and (B) When required under paragraphs (b)(2) and (b)(3) of this section.

(2) Conduct an annual survey to verify the water quality profile of your agricultural water.

(i) After the baseline survey described in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, you must test the water

annually to verify your existing water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest.

(ii) If the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile and, as appropriate, modify your water use based on the new water quality profile in accordance with § 112.44(c)(1) through (3) as soon as practical and no later than the following year. To develop a new water quality profile, you must calculate new GM and STV values using either:

(A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or

(B) Your current annual survey data, combined with new data, to make up a dataset of at least 20 samples; and

(3) If you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in paragraph (b)(2) of this section (for example, if there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the quality of your water source), you must develop a new water quality profile. To develop a new water quality profile, you must calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you must modify your water use based on the new water quality profile as soon as practical and no later than the following year.

(c) If you use untreated ground water for purposes that are subject to the requirements of § 112.44, you must test the quality of each source of the water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected during a time period(s) as close as practical to harvest. If the samples tested meet the applicable microbial standard of § 112.44 (i.e., no detectable generic E.

coli per 100 mL under 112.44(a) or a geometric mean of generic *E. coli* of 126 CFU or less per 100 mL under 112.44(c), as applicable), you may test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. You must resume testing at least four times per growing season or year if any annual test fails to meet the applicable microbial standard in § 112.44.

(d) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard. You must have adequate scientific data or information to support your testing frequency.

(e) You may meet the requirements related to agricultural water testing required under paragraphs (b), (c), and (d) of this section using:
(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or
(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

7. Section 112.50, is amended by adding new paragraphs (b)(8) and (b)(9) to read as follows: § 112.50 Under this subpart, what requirements apply regarding records?
* * * * *
(b) * * *
(8) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that is used to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic E.coli in accordance with the provision in §112.44(c)(2); and
(9) Scientific data or information you rely on to support your testing frequency for untreated surface water used for purposes that are subject to the requirements of § 112.44(a).

**PMA Comments:** PMA believes the FDA has reached numerous erroneous conclusions based on our review of data and facts regarding the safe use of agricultural water for the growing, harvesting, packing and holding of produce for human consumption.

Listed below are specific areas of concern regarding proposed agricultural water provisions of supplemental produce rule.

**Currently Proposed Agricultural Water Provisions are Overly Complex and Overly Prescriptive**

- PMA believes that it is not currently possible to set a single risk-based and science-based quantitative preventive control standard for the use of agricultural water due to lack of technical information and the unknown efficacy of various preventive controls under situational specific conditions. Setting a single quantitative preventive control standard for agricultural water is a "one size fits all" approach because a single quantitative standard would not adequately take into consideration numerous contributing factors that affect the risk of contamination and the probability of subsequent illness. Situation-specific quantitative preventive control standards for agricultural water are desirable but only when there is sufficient situation-specific technical information to provide an appropriate level of guidance to farmers as to the procedures and practices that should be followed to reduce the risk of crop adulteration. FDA has proposed a "one size fits all" approach to safe agricultural water use, which is analogous to applying the time and temperature preventive control needed to pasteurize fluid milk to all fluid beverages. It is simply not appropriate from a risk-based and science-based perspective.
- It is recommended that FDA take the same approach to agricultural water as the agency has taken to regulate the use of raw manure as biological soil amendment of animal origin. In that, the FDA should delay codifying quantitative preventive controls for use of agricultural water.
- PMA would also like to propose that FDA consider use of more flexible regulatory provisions in the agricultural water codified preventive control provisions of the produce safety regulation such as for example, those found in sections 21 CFR 110.80 Processes and Controls – *"Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food."*
- Specifically it is suggested that FDA consider amending § 112.41 as follows for "Agricultural Water" in the produce safety regulation;
    - *"All agricultural water <u>used for the growing, harvesting and packing of produce</u> must be safe and of adequate sanitary quality for its intended use. <u>Agricultural water may be reused for the growing, harvesting and packing of produce if it does not contaminate the food.</u>*
- *"Adequate sanitary quality for its intended purpose"* needs to be defined through FDA Level I guidance in a manner that takes into account the

water source, procedures and practices regarding how the agricultural water is used on the farm and the crop being grown.

- In summary, PMA respectfully requests that at this time FDA not set quantitative microbial water quality standards in the produce rule that rely on generic *E. coli* as an indicator and use the U.S. Environmental Protection Agency (EPA) Recreational Water Quality Criteria (RWQC) as their basis. While use of *E. coli* as an indicator microorganism and use the U.S. EPA RWQC may be appropriate for some produce commodities, these criteria are not appropriate for all commodities.
- If FDA chooses to promulgate quantitative agricultural water quality standards in the final produce rule, it should be done only on an "interim" basis until more science-based and risk-based commodity specific and situation specific standards can developed to account for the diversity of procedures, practices and inherent differences among produce commodities. Additionally and importantly, any interim agricultural water standard should have a "sunset provision" associated with it so as to incentivize industry, government and academia to work to together to investigate and develop science-based and risk-based quantitative agricultural water quality standards that are commodity specific and situation specific that account for the diversity of procedures and practices in agricultural production as well as inherent differences among produce commodities.

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**Use of Generic *E. coli* as Agricultural Water Microbial Quality Indicator is Not Appropriate.**

- PMA believes that the body of scientific knowledge is currently inadequate to establish quantitative metrics based solely on the use of generic *E. coli* as an indicator organism. Hence PMA does not support the use of quantitative generic *E. coli* levels as the criteria in the regulation to determine when agricultural water is or is not of safe and adequate sanitary quality. Monitoring for generic *E. coli* may provide information regarding the potential for overt fecal contamination but it is not a definitive indicator of pathogens in agricultural water. Nor does agricultural water with generic *E. coli* levels below the proposed quantitative criteria mean that the agricultural water is definitively free of human pathogens. However, use of generic *E. coli* as an indicator organism of agricultural water quality may be appropriate for some crops such as lettuce and leafy greens but this quantitative criteria is likely overly protective for many other crops and may not be protective enough in other instances.

- Additionally, as new scientific knowledge becomes available, growers must be able to utilize updated and improved testing and sampling methodologies

that can better assess the safety of the agricultural water that they will use. PMA is concerned that as more information about generic *E. coli* and other indicators become available the quantitative criteria set forth in the proposed produce rule will be obsolete and not protective of public health or overly protective of public health.

In August 2014 the Center for Produce Safety published a five-year research review regarding "Agricultural Water" that can be found at: http://www.centerforproducesafety.org/amass/documents/document/247/CPS%20Ag%20Water%20Research%20Report%202014%20with%20corrections%201.1.pdf The following is excerpted from the above mentioned CPS Agricultural Water report and provides a concise technical summary of why PMA contends that the use of generic *E. coli* as a microbial quality indicator is not appropriate for agricultural water.

*"Because there are many pathogens that can potentially contaminate agricultural water and cause illness if consumed, it is not practical to test for any one pathogen to assess microbial quality. Generic* E. coli*, commonly used as an indicator organism for fecal contamination, is currently used in both recreational water quality standards and drinking water standards as one of several indicators that water is suitable for human contact and consumption. However, despite its use as an indicator of fecal contamination, studies have demonstrated that generic* E. coli *does not consistently correlate with pathogen presence (Benjamin, 2013; Duris, 2009; Edge, 2012; McEgan, 2013; Nieminski, 2010; Vereen, 2013; Wilkes, 2009; Won, 2013a).* L. monocytogenes *was found to have an inverse relationship with fecal indicators (Wilkes, 2009). Benjamin et al. (2013) did not find* Salmonella *or* E. coli *O157:H7 to be correlated with generic* E. coli *concentrations. Studies by Forslund et al. (2012) and Pahl et al. (2013) also found limited association between fecal indicator organisms in irrigation water and the populations on tomatoes.* E. coli *O157:H7 has been found to persist longer in pond water than generic* E. coli *and fecal enterococci most likely due to* E. coli *O157:H7 being less susceptible to environmental stressors like exposure to solar radiation and predation (Jenkins, 2011).* E. coli *has also demonstrated to have the ability to multiply in soil. Hence E. coli concentrations can be artificially elevated above that expected from fecal impacts alone and thus challenges the use of generic* E. coli *as a suitable indicator of water quality in tropical and subtropical environments (Solo-Gabriele, 2000). Regrowth of fecal indicator bacteria in river sediments may also lead to a decoupling of the association between fecal indicator bacteria and human pathogens concentrations in water and thus limit the ability of fecal indicator bacteria as indicator for human illnesses (Litton, 2010)."*

**Use of the U.S. EPA RWQC as Agricultural Water Microbial Quality Indicator is Not Appropriate.**

- Use of the U.S. Environmental Protection Agency (EPA) Recreational Water Quality Criteria (RWQC) as the basis for an agricultural water standard is an extrapolation of the U.S. EPA data set. Specifically, the U.S. EPA RWQC assumes direct personal ingestion of the recreational water and correlates that event to the prevalence of subsequent illnesses. Direct consumer consumption of agricultural water simply does not occur, which makes extrapolation and quantification of the recreational water risk assessment to agricultural water highly questionable and imprecise at best. Use of the U.S. EPA recreational water quality criteria may be appropriate for some crops such as lettuce and leafy greens but this quantitative criteria is likely overly protective for many other crops and may not be protective enough in other instances. It is recommended that appropriate agricultural water quantitative risk assessments be conducted before a quantitative preventive control standard is set in the produce safety regulation or accompanying guidance documents.

**Use of a Geometric Mean and Statistical Threshold Value for Evaluating Agricultural Water Microbial Quality Are Not Universally Appropriate.**

- Currently proposed provisions that require farmers to calculate a geometric mean (GM) and statistic threshold value (STV) to characterize the microbial quality of their agricultural water are overly complex to be accomplished on a regular basis by individual farmers. Additionally the total number of samples required for the agricultural water characterization is excessive in number, economically burdensome and will be problematic from a laboratory capacity perspective. Put simply, as currently proposed, more agricultural water testing will not lead to safer agricultural water, and a lot of mandated agricultural water testing will be occurring with little to no public health benefit.
- Specifically, requiring recalculation of the GM and STV every 10 years using intensive sampling data (minimum total of 20 samples) is a redundant resource intensive activity. If ongoing sampling during the preceding 10 years has repeatedly and consistently demonstrated conformance to the prescribed water quality criteria, intensive sampling should not be required. Use of a rolling GM and STV should be considered *in lieu* of mandatory recalculation every 10 years.

**Agricultural Water Application-to-Harvest Time Interval § 112.44 (c) (1) and Postharvest Application-to-Harvest Time Interval § 112.44 (c) (2)**

- FDA's acknowledgment that pre-harvest and post-harvest agricultural water application-to-harvest time intervals have a significant effect on the microbial composition and risk associated with consumption of fresh

produce is significant as it provides a means for growers to assess the safe use of agricultural water. However, PMA believes FDA has reached erroneous conclusions based on the limited data that was used to support a microbial die-off rate of 0.5 log per day. Microbial die-off rates on produce can be almost universally characterized as a logarithmic decline in microbial populations, with an initial very rapid decline in microbial populations soon after inoculation, followed by a much slower population decline. The proposed pre-harvest application-to-harvest interval microbial die-off rate of 0.5 log per day assumes a constant linear die-off rate when in fact it has been repeatedly established that microbial die-off on fresh produce occurs logarithmically. FDA proposed constant linear microbial die-off rate unbounded by any time constraints is hence problematic, in that it is likely to lead growers to erroneous conclusions regarding the long-term die-off of microbes on produce. For example if a grower were to use a 14-day pre-harvest application to harvest interval, using the proposed microbial die-off rate of 0.5 log per day would mean that a farmer could assume a 7 log reduction in microbes. Based on peer-reviewed and well-documented research studies, including those cited by FDA, a 7 log reduction is highly improbable due to the logarithmic nature of microbial die-off on fresh produce. After review of the source data in reference number 17 (Snellman, E., Marianne, F., Ravaliya, K., and Assar, S., "Memorandum to the File--Review of Microbial Decay Constants Reported in Field Trials of Contaminated Produce," September 2014), it is recommended the microbial die-off rate of 0.5 log per day only be assumed for 4 days after application with a maximum 2 log reduction. Any further extrapolation over a great time period is problematic in that it likely overestimates microbial die-off.

- Requiring farms that use an uncontrolled surface agricultural water source for irrigation, to characterize and routinely monitor the water source seems redundant given that the grower will use mitigation measures to bring their water into compliance, such as using an application-to-harvest interval. This appears to be a duplicative preventive control approach whereby the farmer must continue to monitor the water (one preventive control) when they will be in fact using alternative preventive control (e.g., application-to-harvest interval). PMA suggests that FDA amend the Subpart E, so as to allow growers to use a mitigation measure such as an application-to-harvest interval once they characterize the agricultural water source but not require them to do routine monitoring. This will assure that the preventive control is appropriate yet reduce repetitive costs associated with routine agricultural water monitoring.

**Agricultural Water Data Collected by a Third Party or Parties § 112.45 (e) (2)**

- This provision provides the opportunity for farmers to pool or aggregate resources to reduce burdensome costs associated with the characterization and monitoring of agricultural water. However, PMA requests clarification regarding the following scenario. Farmers, A, B and C all draw agricultural water from a common irrigation canal and rely on a third party to collect, analyze and report the agricultural data to them. Farm D that is directly adjacent to farms A, B and C also draws agricultural water from the common irrigation canal. If the third party who collects, analyzes and reports to farmers A, B and C that their water does not meet the FDA water quality microbial criteria for agricultural water, and Farm D has data to indicate that their water does meet the FDA water quality microbial criteria for agricultural water; may Farm D continue to use this agricultural water source with no mitigation or does Farm D also have to use mitigation measures based on this conflicting data? PMA respectfully requests clarification regarding this situation specific scenario as it is likely to occur possibly due to differences in sampling dates, sampling techniques or other unknown factors.

## d. Subpart F - Biological Soil Amendments of Animal Origin Preventive Controls

**Subpart F**

**§112.56** is amended by removing from paragraph
(a)(1)(i) the phrase “9 months” and adding in its place the phrase “Reserved”;
(a)(4)(i) the phrase “45 days” and adding in its place the phrase “0 days”; and removing and reserving paragraph (b).

**§112.60** is amended by removing paragraphs (b)(1) and (b)(5) and re-designating paragraphs (b)(2), (b)(3), and (b)(4) as paragraphs (b)(1), (b)(2), and (b)(3), respectively.

**PMA Comments:** PMA supports FDA’s deferred decision on an appropriate time interval for the use of raw manure as a biological soil amendment of animal origin until FDA research, risk assessment and other efforts are undertaken to support compost infrastructure development.

PMA also concurs with FDA that the use of raw manure as a soil amendment with short application-to-harvest interval may increase the likelihood of produce contamination

particularly for crops in close proximity to the soil. Hence the implementation of preventive controls associated with the use of raw manure as a soil amendment is an essential element of any on-farm produce safety plan. Development of science-based, application-to-harvest intervals to minimize the likelihood of produce contamination from raw manure that take into account crop-specific production practices and procedures are warranted. However, we do not believe that a single quantitative preventive control standard for application to harvest intervals regarding the use of raw manure is possible to be set in a risk- and science-based manner. The survival of enteric pathogens of public health concern has been demonstrated to be extremely variable in soils amended with raw manure, as pathogen die-off is affected by numerous factors including but not limited to: animal of origin of the raw manure, the amount of manure applied to the field, soil type, climatic conditions, application and post application practices, etc. Therefore we conclude that setting a single quantitative preventive control standard for application to harvest intervals is not likely possible. In summary, there is not one die-off curve for human pathogens of public health concern in soils amended with raw manure but numerous die-off curves whose characteristics are determined by numerous biotic and abiotic factors. The reality of this variability in pathogen survival and risk must be taken into account as standards and guidance are developed by the FDA.

We commend FDA's efforts to set application-to-harvest intervals based on sound research and risk assessments, as only by use of science- and risk-based modeling approaches that account for the numerous inherent variables will farmers be able to make informed decisions regarding the safe use of this important agricultural input.

PMA has concerns that FDA has interpreted the FSMA statute term "enforceable standards" as meaning wherever possible the use of "quantitative standards" in the produce safety rule implementing regulation. It is desirable to have objective quantitative standards set forth in regulations because they are readily measurable, unambiguous and not easily misinterpreted by either regulators or the regulated community. However, in some cases, as is the case with raw manure use as a soil amendment, it is not currently possible to set risk-based and science-based quantitative preventive control standards, due to lack of technical information about the risks posed and the efficacy of various known preventive controls (e.g., application-to-harvest intervals). PMA would like to propose that FDA consider use of qualitative regulatory provisions in the codified provisions of the produce safety regulation such as: *"You must use, handle, convey and store any biological soil amendment of animal origin in a manner that it does not contaminate covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems."* This level of specificity is what is needed in the codified produce safety implementing regulation and compliance for situational specific procedures, and practices should be clearly articulated by the agency in FDA Level I guidance to the industry. If FDA does not take this hybrid approach of broad requirements in the implementing regulation, followed by situational specific guidance, it risks creating a static regulatory requirement for all situations locked in current 2014

science that does not allow for continuous improvement, incorporation of new scientific findings or process innovations.

**PMA Comment:** PMA concurs with FDA's decision that the agency does "not intend to take exception to the continuation of adherence to the National Organic Program (NOP) standard" for use of raw manure. However, PMA believes it is not appropriate for FDA to set an interim standard using the USDA National Organic Program standard set forth in 7 CFR 205.203(c)(1). The USDA NOP sets standards for organic integrity and not product safety and it is demonstrably clear the USDA NOP standard may be overprotective of public health for some crop/practices combinations and under protective of public health for some crop/practices combinations. Setting a "one size fits all" interim standard in the final produce rule would provide a false sense of security in the agricultural community and potentially stifle research regarding this issue. If FDA chooses to promulgate quantitative standard for use of raw manure in the final produce rule, it should be done only on an interim basis until more science-based and risk-based, commodity-specific and situation-specific standards can be developed to account for the diversity of procedures, practices and inherent differences among produce commodities. Additionally and importantly, any interim quantitative standard for use of raw manure in the final produce rule should have a "sunset provision" associated with it so as to incentivize industry, government and academia to work together to investigate and develop science-based and risk-based quantitative standards for the use of raw manure that are commodity specific and situation specific and account for the diversity of procedures, practices in agricultural production, and inherent differences among produce commodities.

**e. Subpart I - Highlighted Protections of Endangered Species**

**Subpart I**

**§ 112.84 Does this regulation require covered farms to take actions that would constitute a "taking" of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?**

No. Nothing in this regulation authorizes the "taking" of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

**PMA Comments:** PMA supports proposed §112.84 to explicitly state that part 112 would not authorize or require covered farms to take actions that would constitute the "taking" of threatened or endangered species in violation of the Endangered Species Act, or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

## f. Subpart R - Withdrawal and Reinstatement of a "Qualified Exemption"

**Subpart R**

**§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?**

(a) We may withdraw your qualified exemption under § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:

(1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 10 calendar days of the date of the notification, to FDA's notification; and

(3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

**§ 112.202 What procedure will FDA use to withdraw an exemption?**

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA

official senior to such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

**§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?**

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN) shall, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved the problems with the conduct or conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

**PMA Comment:** PMA opposes the "qualified exemption" based on revenues and market channels (direct to a consumer, restaurant or retail food establishment) and has repeatedly recommended that this exemption be eliminated.

**PMA Comment:** PMA supports the administrative procedures that FDA has proposed regarding withdrawal of a "qualified exemption."

**PMA Comment:** PMA supports the administrative procedures that FDA has proposed regarding re-instatement of a "qualified exemption" when FDA determines, after finishing an active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to the farm that had its "qualified exemption" withdrawn.

**PMA Comment:** PMA does not support inclusion of administrative procedures for the re-instatement of withdrawn "qualified exemption" in the case where farm has been linked to a foodborne illness outbreak. The FSMA statute does not provide for reinstatement of the "qualified exemption" and FDA should not provide for re-qualification and reinstatement of a withdrawn "qualified exemption." Once a "qualified exemption" has been withdrawn due to a foodborne illness being associated with produce from a specific farm, a permanent withdrawal of the "qualified exemption" should occur, with no possibility for re-instatement.

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